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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,233	12/01/2003	Arne Holm	P63882US1	3256

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EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/724,233	HOLM ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *84-95* is/are pending in the application.

4a) Of the above claim(s) *94 and 95* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *84-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claims 84-93) is acknowledged. The traversal is on the ground(s) that the process of group I can only be used to make the LPA of group II. This is not found persuasive because the process of claim can be used to make other products since the solid phase synthesis can make other products.

The requirement is still deemed proper and is therefore made FINAL.

Claims 90 (with respect to the non-elected species), 94 and 95 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement.

Applicants' election of the following species: C terminal sequence of OspC from Borrelia burgdorferi (Pro-Val-Val-Ala-Glu-Ser-Pro-Lys-Lys-Pro) for H2N-A-COOH and imino diacetic acid for formula II and LPA-I is noted.

Status of Claims

Claims 84-95 are pending

Claims 90, 94 and 95 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species.

Claims 84-94 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 84-94 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. [This is a new matter rejection].

The claim 84 drawn to Formula (I) with the corresponding definitions of each of the variables in said formula; Formula II-Formula VI are not supported in the original disclosure. Likewise the claim to a "plurality of identical, fully side-

chain protected peptide sequences"; "between 4 and 20 naturally occurring L-amino acid residues" are all not supported in the as-filed specification. The as-filed specification does not recite for any compounds of the recited formulae. Cf. original claim 1. MPEP 714.02 clearly states that applicants point out where in the specification support can be found.

Written Description Rejection

Claims 84-94 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy a written description requirement for a claimed genus a sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d

at 1568, 43 USPQ2d at 1406. A representative number of species means that the species, which are adequately described, are representative of the entire genus.

The specification does not describe a method of solid phase synthesis for preparing a ligand presenting assembly (LPA) having undefined amino acids sequences between 4 and 20 amino acids. Furthermore, the specification does not disclose that any achiral dicarboxylic acid with 0.4-0.6 equivalents can be employed in the synthesis of a peptide with no primary sequence. That such amount would result in a peptide with no racemization effect. It is well known in the art that solid phase synthesis would require the amino acid sequences for the synthesis to occur. Given no amino acid structures, it is not clear as to the kind of amino acids or combinations thereof that can be synthesized by solid phase. It is well known in the art that synthesis of longer amino acid sequences may result in ring formation or require activation condition, which could prevent formation of well-defined products with optically active bridging compounds. In biotechnological invention one cannot necessarily claim a genus after only describing a single species because there may be unpredictability in the results obtained from species other than those specifically described. The specification does not describe the correlation between the

species recited therein to the huge scope of the genus having no primary sequences for the claimed peptide sequences.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 87, 89 and 91-93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 87 is unclear as to the term "derived". It is unclear as to how the peptide sequences are derived from OSPC protein of Borrelia. It is a native fragment or a peptide with modification therein? This claim has similar import to claim 89.

2. The representation of e.g., Formula III with "> S" is unclear and confusing as to how it is connected to the other moieties.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 84-86 are rejected under 35 U.S.C. 102(b) as being anticipated by Bhatnagar et al (J. Med. Chem.)

Bhatnagar et al disclose at page 3814, Fig. 1 a method of solid phase synthesis of a dimer as shown at Fig. 1. The complete synthesis is described under Chemistry section, page 3814 up to page 3815. The synthesis uses 0.5 mol equivalents of the diamino dicarboxylic acid. Accordingly, the specific method of Bahtnagar to synthesize a specific compounds using the dicarboxylic acid at 0.5 mol (which is within the claimed range of .4-.6) fully meet the broad claimed method with no define structures for any of the compounds being synthesized.

Claims 84-86 are rejected under 35 U.S.C. 102(b) as being anticipated by Lange et al (J. Pept. Sci.)

Lange discloses a method of solid phase of dimeric peptide Bradykinin containing a diaminodicarboxylic acid linker. See e.g., the abstract at page 289 and the detailed solid phase synthesis at e.g., page 90, Materials and Methods. The method of Lange using specific Bradykinin peptides with dicarboxylic linker fully meets the claimed method of solid phase of a ligand assembly, as broadly claim.

Claims 84-86 are rejected under 35 U.S.C. 102(b) as being anticipated by Alberts(Peptides).

The broad claimed method of synthesizing what appears to be a peptide dimer having any amino acid residues for the peptide sequences is fully met by the specific solid phase synthesis method of Alberts. Alberts discloses at page 367 the synthesis of the hematopoietic peptide of the peptide sequence as shown Fig. 1. The synthesis employs a dicarboxylic acid. Therefore, the solid phase synthesis of the specific dimer peptide sequence of Alberts fully meets the broad claimed method having no primary amino acid sequences.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 84-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Bhatnagar et al (J. Med. Chem.) or Lange in view Mathiesen (WO 97/422210).

Each of Bhatnagar and Lange is discussed above. Each of these references does not disclose applying the solid phase synthesis to a peptide derived from OspC of Borelia burgforferi. However, Mathiesen discloses a method of making a peptide from a sequence of OspC of Borelia burgforferi having the sequence of Seq. ID. 1 and the variants thereof by solid phase synthesis. See e.g., the abstract; page 6, line 20 and pages 34-35 as to the solid phase synthesis of the sequence referring to the method of Holm (1989) and Meldal. Mathiesen discloses that the use of this short peptide which form a part of the antigenic epitope is essential in the human immunological recognition of

OspC (page 4, lines 25-31), which has a number of advantages. For example, it simplifies the preparation and purification steps of the components of the assay and helps standardize the assay. See e.g., page 5, lines 3-35). Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to synthesize in the method of either Bhatnagar or Lange the peptide from OspC of Borelia burgforferi for the advantages taught by Matheisen in the used of said short peptide sequences. One would be motivated to synthesize a dimer for greater immunological responses to said OspC of Borelia burgforferi antigen.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner

Art Unit 1639

tdw
May 26, 2006